UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

Order Granting in Part Defendants' Motion for Summary Judgment

[ECF No. 49]

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4. Heinrich's husband, plaintiff Gregory Heinrich, asserts a claim for loss of consortium. *Id.* This case was recently remanded from the MDL court with several motions pending.

The Heinrichs assert claims for: (1) negligence; (2) strict liability – manufacturing defect; (3) strict liability – failure to warn; (4) strict liability – defective product; (5) strict liability – design defect; (6) common law fraud; (7) fraudulent concealment; (8) constructive fraud; (9) negligent misrepresentation; (10) negligent infliction of emotional distress; (11) breach of express warranty; (12) breach of implied warranty; (13) violation of consumer protection laws; (14) gross negligence; (15) unjust enrichment; and (16) loss of consortium. ECF No. 4. The defendants move for summary judgment on counts 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, and 15.

The plaintiffs respond by withdrawing counts 2, 4, 6, 7, 8, 9, 11, 12, 13, and 15. ECF No. 59 at 1-2. I therefore grant the defendants' motion as to those claims. That leaves only the plaintiffs' count 3 for "strict liability – failure to warn" at issue in this motion.[1] The defendants contend Heinrich has no evidence of causation to support that count.

The parties are familiar with the facts, so I do not repeat them here except where necessary. I deny the defendants' motion as to count 3 because genuine issues of fact remain regarding the adequacy of the defendants' warnings.

I. LEGAL STANDARD

Summary judgment is appropriate if the movant shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a), (c). A fact is material if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

The party seeking summary judgment bears the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to set forth specific facts demonstrating there is a genuine issue of material fact for trial. *Fairbank v. Wunderman Cato Johnson*, 212 F.3d 528, 531 (9th Cir. 2000); *Sonner v. Schwabe N. Am., Inc.*, 911 F.3d 989, 992 (9th Cir. 2018) ("To defeat summary judgment, the nonmoving party must produce evidence of a genuine dispute of material fact that could satisfy its burden at trial."). I view the evidence and reasonable inferences in the

[1] The defendants did not move for summary judgment on counts 1, 5, 10, 14, and 16, so those claims remain.

light most favorable to the non-moving party. *James River Ins. Co. v. Hebert Schenk, P.C.*, 523 F.3d 915, 920 (9th Cir. 2008).

II. ANALYSIS

The defendants contend that Nevada would adopt the learned intermediary doctrine in the context of this case. The defendants assert that under that doctrine, they are immune from Heinrich's failure to warn claim so long as they provided her implanting doctor, Dr. Hsieh, with all relevant safety information for the TVT-S product; it was then up to Dr. Hsieh to convey relevant safety information to Heinrich. They contend that Dr. Hsieh testified that he knew about the risks associated with every injury Heinrich claims to have suffered from implantation of TVT-S and that he advised Heinrich of those risks in a consent form that Heinrich signed prior to surgery. The defendants contend Dr. Hsieh testified additional warnings would not have changed his recommendation of the TVT-S to address Heinrich's SUI. The defendants argue that as a result, they are entitled to summary judgment because Heinrich has no evidence of causation.

The plaintiffs respond that Nevada has not adopted the learned intermediary doctrine in this situation, and I should predict that Nevada would not do so because the policies that led the Supreme Court of Nevada to adopt it with respect to pharmacists does not apply to manufacturers like the defendants. They also argue the doctrine should not apply where a doctor is in a consulting relationship with the manufacturer such that the physician is not exercising his or her independent medical judgment. The plaintiffs contend the defendants compensated Dr. Hsieh to use and teach others to use their products, including TVT-S, and that Dr. Hsieh ceased using the defendants' products once they stopped compensating him to do so. They argue a

reasonable jury thus could find his medical judgment on what device to use was swayed by the defendants' payments to him.

Alternatively, they argue that the learned intermediary doctrine is an affirmative defense that the defendants bear the burden of proving. They contend that to invoke the defense, the defendants must show that Dr. Hsieh was adequately warned. The plaintiffs contend that although Dr. Hsieh understood the risks of mid-urethral mesh sling procedures generally, he was not aware that the TVT-S had higher failure and complication rates than other mesh slings, such as TVT Retropubic (TVT) and TVT Obturator (TVT-O). The plaintiffs argue the defendants were aware of these increased failure rates but failed to warn physicians like Dr. Hsieh, who testified he was not aware of higher failure rates for TVT-S. They also argue the evidence shows that if given this information, Dr. Hsieh would have considered it and in fact he later adjusted his consent forms in response to additional information. They also contend that shortly after receiving this new information, hospitals at which Dr. Hsieh performed his procedures ceased using TVT-S. The plaintiffs contend that if Dr. Hsieh had advised Heinrich of higher complication rates with TVT-S, she would not have agreed to use of the product.[2]

In reply, the defendants argue that the learned intermediary doctrine is not an affirmative defense for which they bear the burden of proof. Rather, they contend, it defines the scope of their duty to the plaintiffs. They also argue the adequacy of the warnings is not relevant to the learned intermediary defense. Finally, they contend it is irrelevant whether Heinrich

[2] The plaintiffs also contend the instructions on how to safely use the product were inadequate because the defendants could not adequately describe how to properly tension the product and the defendants knew their instructions were inadequate. They argue this caused Dr. Hsieh to place too much tension on the sling, resulting in urinary obstruction and urethral erosion. The defendants did not address the instructions for the product's safe use, either in their motion or in their reply. Consequently, I do not address that issue.

would have consented because the question is whether Dr. Hsieh would have recommended the TVT-S regardless of additional warnings.

Under Nevada law,[3] to prove a failure to warn claim, a plaintiff must show: "(1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect caused the plaintiff's injury." *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). "A product may be found unreasonably dangerous and defective if the manufacturer failed to provide an adequate warning." *Rivera v. Philip Morris, Inc.*, 209 P.3d 271, 275 (Nev. 2009) (en banc). The plaintiff bears the burden of proving causation in a strict liability case. *Id.* at 275. A plaintiff can meet that burden "by demonstrating that a different warning would have altered the way the plaintiff used the product or would have prompted plaintiff to take precautions to avoid the injury." *Id.* (quotation omitted).

A. Nevada Would Adopt the Learned Intermediary Doctrine for Strict Products Liability Failure to Warn Claims Against Medical Device Manufacturers

Nevada has adopted the learned intermediary doctrine thus far in only one circumstance: in a negligence action, a pharmacist does not owe a duty to warn a customer of a medication's generalized risks because the physician who prescribed the medication is in the best position to do so. *Klasch v. Walgreen Co.*, 264 P.3d 1155, 1158-59 (Nev. 2011) (en banc). But a pharmacist is required to warn a customer of a customer-specific risk of which he or she knows, such as where the customer is known to be allergic to the prescribed medication. *Id.* at 1160. In that case, the pharmacist must either warn the customer or advise the prescribing physician of the customer-specific risk. *Id.*

[3] The parties agree Nevada law applies. ECF Nos. 50 at 4; 59 at 1.

Nevada has neither adopted nor rejected the doctrine in the context of a medical device manufacturer in a strict products liability failure to warn case. Where Nevada's highest court has not decided an issue, I must predict how that court would decide. *Orkin v. Taylor*, 487 F.3d 734, 741 (9th Cir. 2007). I may use "decisions from other jurisdictions, statutes, treatises, and restatements as guidance." *Assurance Co. of Am. v. Wall & Assocs. LLC of Olympia*, 379 F.3d 557, 560 (9th Cir. 2004) (quotation omitted). Other judges in this district have predicted that Nevada would apply the learned intermediary doctrine to drug and medical device manufacturers. *See, e.g.*, *Flowers v. Eli Lilly & Co.*, No. 3:14-cv-00094-LRH-VPC, 2015 WL 12622058, at *2-3 (D. Nev. July 10, 2015) (holding doctrine applied to drug manufacturer); *Phillips v. C.R. Bard, Inc.*, No. 3:12-cv-00344-RCJ-WGC, 2014 WL 7177256, at *9 (D. Nev. Dec. 16, 2014) (holding doctrine applied to implanted filter manufacturer who had no duty to warn consumer of dangers that it warned physician about).

The plaintiffs argue that the policy reasons underlying *Klasch* do not support applying the doctrine to the manufacturers here. In *Klasch*, the Supreme Court of Nevada concluded that policy considerations supported adopting the doctrine in the context of a pharmacist because "between the doctor and the pharmacist, the doctor is in the best position to warn the customer of a given medication's generalized risks. Or, viewed more pragmatically, the doctrine prevents pharmacists from constantly second-guessing a prescribing doctor's judgment simply in order to avoid his or her own liability to the customer." 264 P.3d at 1159.

Similar policy considerations apply to a medical device manufacturer. As the Supreme Court of Nevada described the doctrine, "so long as the manufacturer has provided the patient's doctor with all relevant safety information" for the device, then it is "up to the patient's doctor—who has the benefit of knowing the patient's specific situation—to convey to the patient any

information that the doctor deems relevant." *Id.* at 1158 (internal footnote omitted). The medical device manufacturer, like the pharmacist, is not in the best position to weigh the risks and benefits of using the device in a particular patient. Rather, "the physician is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999) (quotation omitted). The manufacturer "generally has no ability to assess the suitability of its product for a particular patient in a particular situation," and because the product is usually sent to the doctor or the hospital, "there is no practical way" for the manufacturer to "ensure that the patient receives the written warnings." *Id.* Consequently, I predict Nevada would adopt the learned intermediary doctrine for medical device manufacturers.

B. The Learned Intermediary Doctrine is Not an Affirmative Defense

The parties dispute whether the learned intermediary doctrine is an affirmative defense or whether it defines the scope of the defendants' liability. They relatedly dispute who bears the burden of showing whether the warnings the defendants gave were adequate.

The Supreme Court of Nevada has, in dicta, labeled the doctrine an affirmative defense. *Allison v. Merck & Co.*, 878 P.2d 948, 958 n.16, 969 (Nev. 1994). However, when it adopted the doctrine for pharmacists, it did so in terms of defining the scope of the pharmacist's duties, holding that "Nevada pharmacists have no duty to warn their customers of the generalized risks inherent in the prescriptions they fill." *Klasch*, 264 P.3d at 1159.

Additionally, the Supreme Court of Nevada "has consistently stated that the plaintiff must prove the element of causation" in a strict liability case. *Rivera*, 209 P.3d at 275-76 (rejecting a presumption that a plaintiff would heed a warning if given because it would shift the burden of proving causation to the defendant). Requiring the plaintiff to prove that the warnings

given to the physician were inadequate is in line with Nevada's judgment that the burden of proving causation in these types of cases always lies with the plaintiff. *See Flowers*, 2015 WL 12622058, at *4 (stating that even without the learned intermediary doctrine, the plaintiff could not establish causation because "each doctor or nurse who prescribed Flowers Zyprexa after 2004 did so with knowledge of its metabolic risks, and based on a judgment that those risks were outweighed by the benefits to Flowers' treatment"). Consequently, I predict that the Supreme Court of Nevada would require the plaintiffs to bear the burden of showing the warnings conveyed to Dr. Hsieh were inadequate.

C. Genuine Issues of Fact Remain Regarding the Adequacy of the Warnings

"Although the learned intermediary doctrine frees the manufacturer from warning the end user, the manufacturer still must warn the learned intermediary." *Fisher v. Prof'l Compounding Centers of Am., Inc.*, 311 F. Supp. 2d 1008, 1021 (D. Nev. 2004). The learned intermediary doctrine does not completely insulate a manufacturer simply because it has given some warnings to physicians. Rather, the manufacturer must convey "all relevant safety information for that [device]." *Klasch*, 264 P.3d at 1158; *see also Allison*, 878 P.2d at 956 (stating that a drug is defective if it is not "accompanied by proper directions and warning" (quotation omitted)). A warning may be defective for failing to identify risks as well as for downplaying or understating the disclosed risks. *See Allison*, 878 P.2d at 957-58 (holding that fact questions remained regarding whether the vaccination was defective because although the manufacturer warned of general risks, it did not warn of the possibility of brain damage and it understated the risk of injury); *Phillips*, 2014 WL 7177256, at *9 (holding that fact questions remained regarding whether warnings were adequate where manufacturer gave generalized warnings but knew, and did not warn, "that its own filter had higher rates of failure than typical filters"). The adequacy

of a warning is a question of fact. *Lewis v. Sea Ray Boats, Inc.*, 65 P.3d 245, 249 (Nev. 2003) (en banc).

The plaintiffs have presented evidence from which a reasonable jury could conclude that the TVT-S had higher complication and failure rates than other mesh sling products, that Ethicon knew this but failed to disclose or warn about it, and that Dr. Hsieh was not aware of more complications or failures with the TVT-S as opposed to mid-urethral slings generally. *See, e.g.*, ECF Nos. 59-1 at 12-13; 59-2; 59-3; 59-4 at 131-34; 59-24 at 23-25; 59-25 at 38-42; 59-28. Consequently, whether the warnings were adequate is a question for the jury. *See Flowers*, 2015 WL 12622058, at *4 (denying manufacturer's summary judgment motion in part because there was no evidence the physician was warned about potential side effects until a year or two after it was prescribed to the plaintiff); *Phillips*, 2014 WL 7177256, at *9 (holding issues of fact remained regarding whether manufacturer warned of higher failure rates for particular filter).

D. Genuine Issues of Fact Remain Regarding Whether Dr. Hsieh Would Have Acted Differently in Response to Additional Warnings

The defendants argue that the plaintiffs cannot show causation because Dr. Hsieh testified that he stands by his decision to recommend the TVT-S to Heinrich, and the plaintiffs have no evidence that additional or different warnings would have led him to recommend a different device or procedure. The plaintiffs respond that Dr. Hsieh was aware of the risks of mid-urethral mesh slings generally, but he admitted he was not aware of increased failure and complications rates associated with the TVT-S. They also argue that circumstantial evidence shows Dr. Hsieh in fact changed his behavior in response to information about complications from mesh slings, including no longer using the TVT-S and changing his patient consent form. The plaintiffs also challenge Dr. Hsieh's credibility because he was a paid consultant for Ethicon

and they contend there is a correlation between the products he used in his surgeries and his contracts with Ethicon for teaching other doctors to use specific products.

Dr. Hsieh testified that he stands by his decision to recommend TVT-S to Heinrich and that mid-urethral slings generally were the standard of care for surgically treating SUI. ECF No. 59-4 at 51-58. He also testified that he was well aware of the risks of mid-urethral sling surgeries. *Id.* at 83-84.

However, Dr. Hsieh testified that he was not aware of complications and failures reported in Australia and Germany related to the TVT-S. *Id.* at 131-34. When asked if he would have considered that information in deciding whether to use TVT-S if he had been informed about it, he stated:

> I think if any information was presented that was accurate, I would have reviewed it and that would have been part of the decision-making process in terms of determining what products to offer my patients. But as far as the [Food and Drug Administration (FDA)] in this country, I am fully aware that the product was not deemed as a defective product.

Id. at 134. In October 2008, after receiving an FDA public health notice regarding mesh used in SUI procedures, Dr. Hsieh requested from Ethicon "a copy of the patient labelling for . . . tvt s [sic] to give to patients as recommended by the FDA report." ECF Nos. 59-10; 59-4 at 115-119. Dr. Hsieh also updated his consent procedure by providing mesh implant patients with an additional mesh warning and consent form. ECF Nos. 59-11; 59-12; 59-4 at 118-19. Shortly thereafter, records show that the hospital at which Dr. Hsieh performed his procedures stopped ordering TVT-S. ECF Nos. 59-4 at 130-31; 139-42.

A reasonable jury could conclude from this evidence that Dr. Hsieh would have considered additional information if provided to him—including information on increased failure and complication rates for a particular type of device—when deciding what device to

recommend to his patients and what information to pass on to his patients. Whether Dr. Hsieh would have changed either his recommendation of the TVT-S to Heinrich or the information he provided to her are matters for the jury to resolve, as is Dr. Hsieh's credibility. *Dominguez-Curry v. Nevada Transp. Dep't*, 424 F.3d 1027, 1035-36 (9th Cir. 2005) (stating that credibility is "a determination that is exclusively within the province of the factfinder at trial, not the district court on summary judgment"); *Yamaha Motor Co., U.S.A. v. Arnoult*, 955 P.2d 661, 664-65 (Nev. 1998) (stating that causation is usually a question of fact).

I therefore deny this portion of the defendants' motion. Because I deny the defendants' motion as to count 3, I need not address the plaintiffs' argument that Dr. Hsieh does not qualify as a learned intermediary because he was paid by Ethicon to train other physicians on using TVT-S and so did not exercise independent medical judgment in recommending the device to Heinrich.[4]

III. CONCLUSION

I THEREFORE ORDER that the defendants' motion for summary judgment **(ECF No. 49) is GRANTED in part**. The motion is granted as to counts 2, 4, 6, 7, 8, 9, 11, 12, 13, and 15. The motion is denied as to count 3.

DATED this 17th day of April, 2020.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE

[4] *See, e.g.*, *Talley*, 179 F.3d at 163-64 (stating that for the learned intermediary doctrine to apply, "the physician must be an intervening and independent party between patient and manufacturer" and that a question may arise as to whether a physician is an intermediary if he is "so closely related to [the manufacturer] that he could not exercise independent professional judgment" (quotation omitted)).